## REMARKS

Claims 1-55 are contained in the pending application. Of these claims, claim 1 has been amended to merely incorporate the limitations of claim 2 and claim 2 has subsequently been cancelled; claim 8 has been cancelled based upon the Examiner's rejection (paragraph no. 4, paper 20081508). Claims 13 and 25 have been amended to overcome objections based upon formalities in the claim language. The Applicants do not understand the Examiner's objection to the "third comma in line 4" which the Examiner wants changed to "or." All amendments have been made in furtherance of the prosecution of the case and the Applicants request that the Examiner enter these amendments and make them of record.

## Rejections Under 35 U.S.C. §112, second paragraph

The Examiner has rejected claim 8 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. This claim has now been cancelled rendering this rejection moot.

## Rejections Under 35 U.S.C. §103(a)

The Examiner has repeated his series of 103(a) rejections from the previous office action (paper no. 20080221). These rejections include:

The Examiner has rejected claims 1-39 and 49-55 under 35 U.S.C. §103(a) as being unpatentable over Grijpma et al. (USP 5,672,367). This is the same rejection as set forth in paragraph no. 6, paper no. 20080221. In repeating this rejection, the Examiner continues to maintain that since Grijpma et al. discloses a chewing gum

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including one or more biodegradable polymers as well as conventional chewing gum ingredients and active agents, finding the optimum amount of water and flavoring agents to include in the chewing gum would require nothing more than routine experimentation by one reasonably skilled in the art.

The Examiner has also once again rejected claims 40-48 under 35 U.S.C. §103(a) as being unpatentable over Grijpma et al. (USP 5,672,367), in further view of Meyers. This rejection was set forth in the previous office action (paragraph no. 7, paper no. 20080221). In repeating this rejection, the Examiner continues to argue that it would have been obvious to coat the chewing gum in Grijpma et al. with a coating as claimed by the Applicant in order to provide storage stability to the chewing gum.

The Examiner has also repeated his earlier rejection of claims 1-30, 32-42, 46, 47 and 49-55 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. (WO 01/47368). This rejection was set forth in the previous office action (paragraph no. 8, paper no. 20080221). The Examiner continues to maintain that finding the optimum amount of water and flavoring agents would require nothing more than routine experimentation by one reasonably skilled in the art.

Additionally, the Examiner has repeated his rejection of claim 31 as being unpatentable over Goldberg et al., in view of Grijpma et al., arguing that it would have been obvious to include a medicinal/pharmaceutical ingredient in the chewing gum. This rejection was set forth in the previous office action (paragraph no. 8, paper no. 20080221).

The Examiner has also once again rejected claims 43-45 and 48 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. in view of Meyers.

The Applicants respectfully traverse this series of rejections and each of these will be discussed. in-turn.

As an initial matter, in response to the Applicant's arguments filed May 12, 2008, the Examiner argued that "[a]pplicant's claimed water content is merely an obvious matter of choice depending upon: (i) desired results; (ii) personal preference; (iii) consumer appeal; and (iv) in the absence of unexpected results, via a comparison between the Applicant's claimed water content and the (v) water content disclosed in each primary reference which is closest to the amount claimed by the applicant, can be accorded no patentable weight." Each of these points will be addressed.

#### (i) Desired Results:

Grijpma et al. is directed to a chewing gum comprising certain degradable polymers (see claims 1-8 of Grijpma et al.). Goldberg et al. is directed to a gum base comprising certain degradable polymers (claim 1-16 of Goldberg et al.). In particular, claim 15 of Goldberg et al. claims a desired higher water content. In order to obtain a "desired result," i.e., a biodegradable chewing gum or gum base, one should, according Grijpma et al. and Goldberg et al., use certain degradable polymers. Accordingly, if a person skilled in the art wants to prepare a degradable chewing gum and looks to either Grijpma et al. or Goldberg et al., s/he would consider polymer content and not water of the chewing gum, as both Grijpma et al. or Goldberg et al. are silent as to critical water content for the chewing gum and/or gum base.

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### ii) Personal Preference

The Applicant does not understand what the Examiner intends by use of the term "personal preference." The "personal preferences" of Grijpma et al. and Goldberg et al. are to use certain degradable polymers which are suitable for a gum base and chewing gum. If "personal preference" should relate to a specific water content, it is unclear how one skilled in the art would glean such "personal" information from either Grijpma et al or Goldberg et al. One skilled in the art reading Grijpma et al. would readily understand that water content is arbitrarily governed (much less "chosen") by selection of certain water-containing ingredients. Further, since Goldberg et al. seems to favor a higher water content, it is difficult to envision how one skilled in the art would arrive at the chewing gum defined by claim 1 based on their "personal preference."

# iii) Consumer Appeal

According to Grijpma et al. and Goldberg et al., "consumer appeal" relates to chewing gum texture, since the polymers used determine the texture of the chewing gum and Grijpma et al. and Goldberg et al. are directed to the use of specific polymers (see for instance Goldberg et al., p. 2, lines 9-21; and Grijpma et al., col. 2, lines 5-9). It is not clear how a person skilled in the art, based upon Grijpma et al. and Goldberg et al. would arrive at the chewing gum defined by claim 1 of the pending application as one having "consumer appeal."

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iv) Absence of unexpected results

The Examiner is impermissibly using hindsight when he asserts that The Applicant's limiting of the pre-chew degradation of the chewing gum polymers by keeping the water content of the chewing gum within a certain range (as in newly amended claim 1) and, at the same time, obtaining a desired texture, is not an unexpected result. None of the primary references cited by the Examiner identifies the problem which is identified and solved in the pending application. In order to emphasize that *small* amounts of water are beneficial for the texture of the chewing gum of the present invention, claim 1 has been amended such that it now requires that the water content of the chewing gum be within a certain range which constitutes a trade-off between limiting pre-chew degradation and promoting the desired texture.

v) The water content disclosed in each primary reference

The water content per se' is not disclosed in any of the primary references and it is therefore not possible to make any specific comparisons, as suggested by the Examiner. Example 13 in the pending application compares a biodegradable chewing gum containing about 1.5% water, by weight, with biodegradable chewing gum containing about 0.5% water, by weight. This comparison shows that the shelf life of the biodegradable chewing gum with the lower water content is significantly better than shelf life of the biodegradable chewing gum with the higher water content. In addition, it has been shown that for certain applications, the degradation rate of the chewing gum having a water content of about 1.5%, by weight, may be acceptable.

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Thus, the allowable upper limit for the water content, as recited in newly amended claim 1 is 2.0%, by weight.

## vi) The Primary References

The Examiner has rejected claims 1-39 and 49-55 as being obvious in view of Grijpma et al. The Applicants traverse this rejection.

Grijpma et al. does not disclose or claim a required water content for the degradable chewing gum. Grijpma et al. is also silent as to the problem of degradation of the chewing gum polymers prior to chewing by the consumer. This problem of pre-chew degradation is successfully solved in the pending application through the use of a low-water content gum and surprisingly, an acceptable texture of the resulting chewing gum is obtained (see pending application, p. 2, lines 10-22). There are no teachings or disclosures in Grijpma et al. that would lead one skilled in the art to believe that a low water content gum can also have the desired texture. As maintained by the Applicants in their response filed May 21, 2008, the chewing gum of Grijpma et al. has a water content considerably higher than that claimed in amended claim 1.

In addition, Example 13 in the pending application illustrates the effect of low water content, which is greater storage stability of the biodegradable chewing gum, while still maintaining a suitable texture.

The Examiner's contention that "finding the optimum amount of water to be included in the chewing gum would require nothing more than routine experimentation by one reasonably skilled in the art" is clearly based on hindsight, since the problem solved in the pending application is not even disclosed or suggested to be a potential problem by Grijpma et al.

Accordingly, claim 1, as currently amended, is not obvious in view of Grijpma et al.

The Examiner has again rejected claims 1-30, 32-42, 46, 47 and 49-55 as being obvious in view of Goldberg et al. The Applicants respectfully traverse this rejection. Goldberg et al. focuses on certain degradable polymers which would be suitable for a gum base. The issues of pre-chew degradation of a chewing gum defined by claim 1 of the pending application are not addressed in Goldberg et al. Further, one reading Goldberg et al. would not be motivated to utilize a low water content for a biodegradable chewing gum. To the contrary, and as previously argued by the Applicants, Goldberg et al. teaches a higher water content of the chewing gum and clearly *teaches away from* the pending application (see Goldberg et al., p. 15, lines 9-13 and claim 15). In contrast, example 13 of the pending application illustrates the effect of low water content - which is greater storage stability of the biodegradable chewing gum while retaining the desired texture.

The Examiner's contention that "finding the optimum water content in the chewing gum would require nothing more than routine experimentation by one reasonably skilled in the art" is impermissibly based upon hindsight, since the problem solved by the pending application is not even mentioned by Goldberg

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et al. Accordingly, claim 1, as currently amended, is not obvious in view of

Goldberg et al.

The Applicants continue to maintain that Meyers and/or Li et al. in view of

Grijpma et al. and Goldberg et al. provide no additional suggestions or indications as

to how to successfully address the pre-chew degradation or shelf-life issue.

Therefore, the teachings of Grijpma et al., Meyers, Goldberg et al. and Li et al.

do not teach, suggest or motivate one skilled the art to have a biodegradable chewing

gum can have a water content of less than 2% and still expect that it possess the same

desired texture qualities of a traditional, non-biodegradable chewing. In fact, these

references teach away from low moisture (water) content chewing gums, because one

skilled in the art would know that water content is critical in giving the gum its

necessary tactile and texture qualities, which are important to the consumer.

Consequently, in view of the above arguments, the rejections under 35 U.S.C.

 $\S 103(a)$ , have been overcome and should be withdrawn.

**Double Patenting Rejection** 

Claims 1-55 have once again been rejected under the judicially created

doctrine of obviousness-type double patenting as being unpatentable over claims 1-62

of co-pending US application 10/472,122; claims 1-54 of co-pending US application

10/472,154; claims 1-67 of co-pending US application 10/528,926; claims 1-64 of co-

pending US application 10/528,930; claims 1-57 of co-pending US application

10/528,957; claims 1-20, 22-26, and 28-42 of co-pending US application 10/529,133;

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and claims 1, 2, 10, 11, 13-18, 24-26, and 28-54 of co-pending US application 11/088,109.

Upon indication of allowable subject matter in this case, Applicants will file the appropriate terminal disclaimers in order to overcome these rejections.

The present application as amended herein, is now in form for allowance and early reconsideration and allowance of the claims, as currently pending, is earnestly solicited.

Respectfully submitted,

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## CERTIFICATE OF ELECTRONIC FILING

I hereby certify that this correspondence is being electronically filed with The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, this

4th day of December 2008.